The HHS Office of Information Resource Management (OIRM) within the Office of the Assistant Secretary for Management and Budget presents this annotated version of the OMB instructions for preparing a Supporting Statement to provide guidance on the types of information that should be included in each item. OIRM has adapted materials prepared by ACF, NIH and others for Departmental use.

Words in bold print are those of the OMB specifications. Other material is specific guidance about expected contents of each section.

Every effort should be made to keep the Supporting Statement to a length of 10-12 pages. When possible, detailed information should be placed in an attachment, which is then referenced in an appropriate place in the Supporting Statement so that interested reviewers can peruse it. Each attachment should be referenced in the text, so that a reviewer knows why it has been included and which portions may be of particular interest. Brevity and clarity with respect to both the text of the Supporting Statement and any attachments are highly desirable; only the information requested by the OMB outline and needed to understand the project should be included.

THE SUPPORTING STATEMENT

General Instructions

A Supporting Statement, including the text of the notice to the public required by 5 CFR 1320.5(a)(1)(iv) and its actual or estimated date of publication in the Federal Register, must accompany each request for approval of a collection of information. The Supporting Statement must be prepared in the format specified below, and must contain the information specified in Section A below. If an item is not applicable, provide a brief explanation. When item 17 of the OMB Form 83-I is checked "Yes", Section B of the Supporting Statement must be completed. OMB reserves the right to require the submission of additional information with respect to any request for approval.

A. Justification.

1. Explain the circumstances that make the collection of information necessary. Identify any legal or administrative requirements that necessitate the collection. Attach a copy of the appropriate section of each statute and of each regulation mandating or authorizing the collection of information.

   - If the submission is for the approval of regulatory language, this section should specifically state that an approval of the information collection requirements contained in the regulation is requested in addition to any request for approval of information collection forms. Each part of the regulation that contains a collection of information requirement should be separately identified and briefly summarized.

   - If information is being collected for multiple agencies, the need that each agency has for the information should be explained.

2. Indicate how, by whom, how frequently, and for what purpose the information is to be used. Except for a new collection, indicate the actual use the agency has made of the information received from the current collection.

   - The information in this section and in 1. above will be the backdrop for reviewers to use in assessing the appropriateness and adequacy of the sample design, data collection plans and analysis plans. Make sure the need/uses of the information collection are consistent with the design (i.e. don't promise more than the information collection can deliver).

   - Specific, concrete examples of how the information is or has been used should be given, if the request is for an information collection that has been approved previously, or how it will be used if it is a new activity. Care should be taken

to avoid broad, general statements about research, or descriptive analyses. There should be some specific planned use, by some Federal program, for the resulting information. This material is important, because projects are sometimes disapproved on the basis that they lack "practical utility."

3. Describe whether and to what extent, the collection of information involves the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g. permitting electronic submission of responses, and the basis for the decision for adopting this means of collection. Also describe any consideration of information technology used to reduce burden.

4. Describe efforts to identify duplication. Show specifically why any similar information already available cannot be used or modified for use for the purpose(s) described in 2 above.

   o There may be no formal efforts to identify duplication because program staff, through extensive contacts with organizations and individuals in both the private and public sectors, know that there are no similar data known to be available. If no formal effort has been made, a statement about these types of contacts is appropriate.

   o Literature searches and contacts with staff of other organizations should have occurred in other instances. As appropriate, these efforts to identify similar existing information should be described.

   o In many instances there is no similar information; if so, it is fine to state that this is the case. If there is similar information, but it does not meet the current needs of the proposed study, its existence should be acknowledged and the importance of obtaining the information in the proposed study should be stated so that it is clear why the other data will not suffice.

5. If the collection of information impacts small businesses or other small entities (item 15 of the OMB Form 83-I), describe any methods used to minimize burden.

   o OMB encourages development and use of "short forms" for information collection from small organizations. Most information collections require the full range of information from all selected organizational respondents. If, in fact, it is the case that a small organization will skip more of the questions than a large organization, that type of minimization should be cited. At a minimum, it can usually be stated that the information being requested or required has been held to the absolute minimum required for the intended use.

6. Describe the consequence to Federal program or policy activities if the collection is not conducted or is conducted less frequently, as well as any technical or legal obstacles to reducing burden.
   - o For a one-time collection, it is appropriate to simply state: This is a one-time collection.
   - o For on-going collections, explain why the chosen frequency of collection is required.

7. Explain any special circumstances that would cause an information collection to be conducted in a manner:

   Requiring respondents to report information to the agency more often than quarterly;

   Requiring respondents to prepare a written response to an information collection request or requirement in fewer than 30 days after receipt of it;

   Requiring respondents to submit more than an original and two copies of any document;

   Requiring respondents to retain records, other than health, medical, government contract, grant-in-aid, or tax records, for more than three years;

   In connection with a statistical survey, that is not designed to produce valid and reliable results that can be generalized to the universe of study;

   Requiring the use of a statistical data classification that has not been reviewed and approved by OMB;

   That includes a pledge of confidentiality that is not supported by authority established in statute or regulation, that is not supported by disclosure and data security policies that are consistent with the pledge, or which unnecessarily impedes sharing of data with other agencies for compatible confidential use;

   Requiring respondents to submit proprietary, trade secret, or other confidential information unless the agency can demonstrate that it has instituted procedures to protect its confidentiality to the extent permitted by law;

   - o Methodological and developmental studies may not provide results that can be generalized to the universe of study. It is important to recognize such a limitation and justify it here.

- o If a waiver is requested of the limit of requiring not more than an original and two copies of any document, there must be a compelling statement of the need for additional copies, a description of the use to be made of each copy to be requested, and a statement of the negative impact on the public of not being able to obtain the additional copies.

8. If applicable, provide a copy and identify the date and page number of publication in the Federal Register of the agency's notice, required by 5 CFR 1320.8(d), soliciting comments on the information collection prior to submission to OMB. Summarize public comments received in response to that notice and describe actions taken by the agency in response to these comments. Specifically address comments received on cost and hour burden.

   Describe efforts to consult with persons outside the agency to obtain their views on the availability of data, frequency of collection, the clarity of instructions and record keeping, disclosure, or reporting format (if any), and on the data elements to be recorded, disclosed, or reported.

   Consultation with representatives of those from whom information is to be obtained or those who must compile records, should occur at least once every three years - even if the collection of information activity is the same as in prior periods. There may be circumstances that may preclude consultation in a specific situation. These circumstances should be explained.

   - o Consultation within HHS should be encouraged. If a project relates to another Federal program within or outside HHS or impacts it in<u>any</u> manner there should be documentation of consultation with representatives of that program.

   - o There should be a direct statement to the effect that there are no unresolved issues. Of course, if this is not true, and there is an unresolved issue such a statement should not be made. If there is an honest difference of opinion, with no "right" or "wrong" answer, or if a potentially preferable approach cannot be followed because of some overwhelming reason it should be so stated and explained.

9. Explain any decision to provide any payment or gift to respondents, other than renumeration of contractors or grantees.

   - o Any plan for remuneration of respondents must be justified. It is important to provide results of prior methodological studies showing that remuneration in the amount planned is necessary to achieve adequate response rates or to obtain reliable data; the study cited <u>MUST</u> be similar to the one proposed. A copy of

a report of study findings or a free copy of a report is not considered remuneration for these purposes.

10. Describe any assurance of confidentiality provided to respondents and the basis for the assurance in statute, regulation, or agency policy.

- o If you plan to collect identifiable information, explain what methods will be used to maintain the privacy and/or confidentiality of the respondent. Discuss the arrangements for handling, storage, and disposition of the information. Where a contractor is collecting the information, rather than HHS staff, the contractor's procedures for confidentiality should be referenced and appended.

- o It is seldom possible to give respondents a complete assurance of confidentiality. There should be no promise of total and absolute confidentiality for individually identifiable information unless there is a firm legal basis for withholding information in the face of a subpoena or court order or other Federal, state or local legislation.

- o Inclusion in a system of records under the Privacy Act does not of itself provide sufficient protection to warrant assurance of confidentiality to respondents.

11. Provide additional justification for any questions of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private. This justification should include the reasons why the agency considers the questions necessary, the specific uses to be made of the information, the explanation to be given to persons from whom the information is requested, and any steps to be taken to obtain their consent.

- o In addition to the items mentioned, the Department of Health and Human Services has a listing of topics it considers to be sensitive. The following categories are considered to be sensitive:

  -- community activities of a character which indicate political affiliation and attitudes;

  -- mental and psychological problems potentially embarrassing to respondents;

  -- illegal, anti-social, self-incriminating and demeaning behavior;

  -- critical appraisals of other individuals with whom respondents have close relationships, e.g., family, pupil-teacher, employee-supervisor;

-- legally recognized privileged and analogous relationships, such as those of lawyers, physicians and ministers;

-- records describing how an individual exercises rights guaranteed by the First Amendment.

Inclusion of items on any of these topics requires thorough explanation of why it is essential that the Department obtain the information for the study.

- o If it is necessary to obtain Social Security Numbers for a study, the necessity for such inquiry should be explained here. There are specific requirements that must be met when asking individuals for their Social Security Number; these requirements are specified by the Privacy Act. The statement explaining these requirements when the Social Security Number is requested should be printed on the questionnaire. When the Social Security Number is requested, the respondent must be told the legislation that authorizes the request, the uses that will be made of the number, whether its provision is voluntary or not, and the consequences (if any) of not providing the number.

- o Similarly, if the Medicare or Medicaid number is requested for individuals, the same information given when the Social Security Number is sought must be provided to the respondent at the time the number is requested. These benefit programs are under the auspices of the Department of Health and Human Services and every effort must be made to inform respondents how the number will be used and to assure them that provision of the number will have no effect in any way on benefits from the programs.

- o The steps to be taken to safeguard the documents or files containing potentially sensitive information should be described. This may include collecting the information in a totally private setting, removing personal identifiers from completed questionnaires, locked files and rooms for storage of documents and other special steps.

- o Written informed consent is not required, but all steps taken to fully and fairly inform respondents about the nature of the study, any voluntary aspects of their participation, any known benefits to them or to others from participation, any known consequences or side effects of participation, and the extent to which confidentiality of identifiable information can be assured should be described. If this information is contained in a formal consent statement, that consent statement should be summarized in the Supporting Statement and included as an attachment.

12. Provide estimates of the hour burden of the collection of information. The statement should:

Indicate number of respondents, frequency of response, annual hour burden, and an explanation of how the burden was estimated. Unless directed to do so, agencies should not conduct special surveys to obtain information on which to base hour burden estimates. Consultation with a sample (fewer than 10) of potential respondents is desirable. If the hour burden on respondents is expected to vary widely because of differences in activity, size, or complexity, show the range of estimated hour burden, and explain the reasons for the variance. Generally, estimates should not include burden hours for customary and usual business practices.

If the request for approval covers more than one form, provide separate hour burden estimates for each form for which approval is sought and aggregate the hour burdens in Item 13 of OMB Form 83-I.

Provide estimates of annualized cost to respondents for the hour burdens for collections of information, identifying and using appropriate wage rate categories. The cost of contracting out or paying outside parties for information collection activities should not be included here. Instead, this cost should be included in Item 14.

- It is usually helpful to provide this information in tabular manner, with various reporting/record keeping requirements or data collection instruments used as the stub and with headings for the columns that show at a minimum the number of respondents, the number of responses per respondent, the average hours of burden per response, and total burden. This might look as follows:

Form name	No. of Respondents	No. responses per respondent	Hrs. per response	Response burden
Form A	10	5	0.1	5
Form B	2	1	2.0	4
TOTAL	12			9

- The time involved including pulling records from files, abstracting information, returning records to files and assembling any other information necessary to provide the requested information should be included in this estimate.

- The burden estimates shown in this item must also be consistent with the burden disclosure statements included in the preamble to a Notice of Proposed Rulemaking or a final regulation, and/or on the information collection forms or instructions.

- o If an agency chooses to use the burden disclosure statement expressing a range of burden, then the average burden should be stated and used in the burden calculations of this item.

- o The basis for the estimate of burden should be stated. The basis for the estimate may be a formal pre-test or it may be informal testing in the office. It may be experience with prior or current similar activities, or it may be information obtained from potential respondents.

13. Provide an estimate of the total annual cost burden to respondents or record keepers resulting from the collection of information. (Do not include the cost of any hour burden shown in Items 12 and 14).

The cost estimate should be split into two components: (a) a total capital and start-up cost component (annualized over its expected useful life), and (b) a total operation and maintenance and purchase of services component. The estimates should take into account costs associated with generating, maintaining, and disclosing or providing the information. Include descriptions of methods used to estimate major cost factors including system and technology acquisitions, expected useful life of capital equipment, the discount rate(s), and the time period over which cost will be incurred. Capital and start-up cost include, among other items, preparation for collecting information such purchasing computers and software; monitoring, sampling, drilling and testing equipment; and record storage facilities.

If cost estimates are expected to vary widely, agencies should present ranges of cost burdens and explain the reasons for the variance. The cost of purchasing or contracting out information collection services should be a part of this cost burden estimate. In developing cost burden estimates, agencies may consult with a sample of respondents (fewer than 10), utilize the 60-day pre-OMB submission public comment process and use existing economic or regulatory impact analysis associated with the rulemaking containing the information collection, as appropriate.

Generally, estimates should not include purchases of equipment or services, or portions thereof, made: (1) prior to October 1, 1995, (2) to achieve regulatory compliance with requirements not associated with the information collection, (3) for reasons other than to provide information or keep records for the government, or (4) as part of customary and usual business or private practices.

- o It may be stated that there are no direct costs to respondents other than their time to participate in the study. On the other hand, if there are other direct costs to respondents they should be explained and quantified.

14. Provide estimates of annualized cost to the Federal government. Also, provide a description of the method used to estimate cost, which should include quantification of hours, operational expenses (such as equipment, overhead, printing, and support staff) and any other expense that would not have been incurred without this collection of information. Agencies also may aggregate cost estimates from Items 12, 13, and 14 in a single table.

    - Include costs of information collection, design, development, tests, printing forms, mailing list compilation and maintenance, mailing or enumeration, editing, coding, tabulation, analysis and publication of results. Costs, such as salaries and travel, of agency staff involved in project development, implementation, and monitoring should be included.

15. Explain the reasons for any program changes or adjustments reported in Items 13 or 14 of the OMB Form 83-I.

    - For a new collection of information, simply state that this is a new collection of information.

    - For an ongoing collection of information explain the reason/s for any increase or decrease in the annual burden. Any change in the burden estimate must be categorized as a program change or an adjustment, or allocated between the two explanations. Regardless of what has previously been said about changes in the number of respondents or the burden imposed, a clear statement must be given that explains exactly how the burden change has come about.

16. For collections of information whose results are planned to be published, outline plans for tabulation and publication. Address any complex analytical techniques that will be used. Provide the time schedule for the entire project, including beginning and ending dates of the collection of information, completion of report, publication dates and other actions.

17. If seeking approval to not display the expiration date for OMB approval of the information collection, explain the reasons that display would be inappropriate.

18. Explain each exception to the certification statement identified in Item 19, "Certification for Paperwork Reduction Submissions," of OMB Form 83-I.

B. Collections of Information Employing Statistical Methods

The agency should be prepared to justify its decision not to use statistical methods in any case where such methods might reduce burden or improve accuracy of results. When

item 17 is checked "Yes," the following documentation should be included in the supporting statement to the extent that it applies to the methods proposed:

1. Describe (including a numerical estimate) the potential respondent universe and any sampling or other respondent selection method to be used. Data on the number of entities (e.g., establishments, State and local government units, households or persons) in the universe covered by the collection and in the corresponding sample are to be provided in tabular form for the universe as a whole and for each of the strata in the proposed sample. Indicate expected response rates for the collection as a whole. If the collection had been conducted previously, include the actual response rate achieved during the last collection.

    - As a general rule for obtaining OMB approval, the minimum acceptable response rate for a statistical survey is 75 percent and an expected response rate of less than 75 percent requires special justification. As a general rule, statistical data collection activities having an expected response rate of under 50 percent should not be undertaken.

2. Describe the procedures for the collection of information including:

    Statistical methodology for stratification and sample selection,

    Estimation procedure,

    Degree of accuracy needed for the purpose described in the justification,

    Unusual problems requiring specialized sampling procedures, and

    Any use of periodic (less frequent than annual) data collection cycles to reduce burden.

    - A probability sample is always preferred. When a probability sample is not used there should be a full explanation of the rationale and of the rationale for and procedures to be used in the proposed non-probability sample.

    - Precision requirements for estimates from sample surveys should be included. There should be enough detail to enable a reviewer to determine whether proposed sample sizes are sufficient to satisfy the stated requirements.

    - It is important to provide sufficient information about the types of individuals, and any special qualifications they may have, who will collect the information and how it will be done that a reviewer can understand how the sampling plan and data collection instruments are implemented to provide the resultant data.

Any response cards or other visual aids used with respondents must be included in the submission.

- o If advance appointments will be made prior to visit of an interviewer explain that, or if advance letters are sent to respondents mention them and include copies for review and approval.

- o Any quality control procedures to be implemented as part of the field work or review of data coding and preparation should be described. If respondents are re-interviewed or re-contacted, the data collection instrument or script for that re-contact must also be included as an attachment and the burden included.

- o Plans for imputation of missing data should be discussed, and the estimation (including variance estimation) procedures to be used should be described. If commercially available packages will be used for variance computations the name of the computer program should be given.

3. Describe methods to maximize response rates and to deal with issues of non-response. The accuracy and reliability of information collected must be shown to be adequate for intended uses. For collections based on sampling, a special justification must be provided for any collection that will not yield "reliable" data that can be generalized to the universe studied.

   - o If virtually the same study has been done in the past few years, it is appropriate to use that experience as the basis for the expected response rate to the proposed data collection activity, provided techniques used in the earlier experience are not changed in the proposed activity.

   - o It may be appropriate to reiterate briefly the combination of data collection methods, type of respondents, type and amount of information requested, procedures for follow-up of initial non-respondents and refusals, and planned remuneration that are to be used to achieve the stated response rate. The key here is that the accuracy and reliability of the information obtained must be adequate <u>for the intended uses</u>.

4. Describe any tests of procedures or methods to be undertaken. Testing is encouraged as an effective means of refining collections of information to minimize burden and improve utility. Tests must be approved if they call for collection of identical information from 10 or more respondents. A proposed test or set of tests may be submitted for approval separately or in combination with the main collection of information.

- o If a pretest involving fewer than 10 respondents has been conducted and is considered adequate for the purposes of the study it may be so stated.

- o If the data collection procedures and instruments are virtually identical to ones used previously with satisfactory results, it is usually sufficient to state that this is the case.

- o A pretest designed to make significant decisions about data collection method, content, timing or other major aspect of the effort should be submitted for approval separately from the main survey. If only "fine tuning" changes to the data collection activity are expected as a result of the pretest, it is reasonable to seek a combined approval for the pretest and the main survey. OMB must be informed of any changes to the survey procedures or data collection instruments before data collection begins. This information can be communicated by memorandum to OMB, with a copy of the "final" version of the data collection instruments.

5. Provide the name and telephone number of individuals consulted on statistical aspects of the design and the name of the agency unit, contractor(s), grantee(s), or other person(s) who will actually collect and/or analyze the information for the agency.

    - o If the name of the contractor is not yet known because the clearance is being sought prior to the award of the contract, a statement may be made to the effect that a competitive contract will be awarded.